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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,376	03/09/2001	Gary Van Nest	377882001700	8397
25226	7590	12/16/2004	EXAMINER	
MORRISON & FOERSTER LLP			ZARA, JANE J	
755 PAGE MILL RD			ART UNIT	
PALO ALTO, CA 94304-1018			PAPER NUMBER	

1635

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/802,376

Applicant(s)

NEST ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 12-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-11, 57-66 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Pursuant to 37 C.F.R. 1.142(a), whereby the distinctness and independence of the inventions of the instant application have become clear upon further consideration, an examiner's action on the merits of the amendments and arguments filed by applicant on 9-23-04 insofar as they pertain to the elected invention is hereby deferred until an election has been made. (See MPEP 810.02 and 811)

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 4, 6-11, 56, 57, 59, 61-66, drawn to pharmaceutical compositions comprising a liquid, covalently linked, immunostimulatory polynucleotide/microcarrier complex, classified in classes 424, 435 and 536, subclasses 1.53, 458 and 23.1, respectively.
- II. Claims 1, 3, 4, 6-11, 56, 58, 59, 61-66, drawn to pharmaceutical compositions comprising a liquid, non-covalently linked, immunostimulatory polynucleotide/microcarrier complex, classified in classes 435 and 536, subclasses 458 and 23.1, respectively.
- III. Claims 1, 2, 5-11, 56, 57, 60-66, drawn to pharmaceutical compositions comprising a solid, covalently linked, immunostimulatory polynucleotide/microcarrier complex, classified in classes 424 and 536, subclasses 1.53 and 23.1, respectively.

- IV. Claims 1, 3, 5-11, 56, 58, 60-66, drawn to pharmaceutical compositions comprising a solid, non-covalently linked, immunostimulatory polynucleotide/microcarrier complex, classified in classes 424 and 536, subclasses 1.53 and 23.1, respectively.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II and III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the compositions of Groups I-IV are chemically, structurally, biologically and functionally distinct from each other and thus one does not render the other obvious. The composition of Group I is not required to produce the compositions of the other Groups, and vice versa (e.g. The immunostimulatory polynucleotide that is covalently linked to the liquid microcarrier complex of Group I is not required to make the composition of a immunostimulatory polynucleotide non-covalently linked to the liquid microcarrier complex of Group II. Likewise, the immunostimulatory polynucleotide that is covalently linked to the solid microcarrier complex of Group III is not required to make the composition of an immunostimulatory polynucleotide non-covalently linked to the solid microcarrier complex of Group IV, nor is it required to make the compositions of immunostimulatory polynucleotides either covalently or non-covalently linked to the liquid microcarriers of Groups I and II, respectively.) The complexes are chemically distinct and different (e.g. liquid (Groups I, II) versus solid

microcarriers (Groups III, IV); covalent linkage between polynucleotides and microcarriers (Groups I and III) versus non-covalent linkage between polynucleotides and microcarriers (Groups II and IV). For these reasons, the inventions of Groups I, II, III and IV are patentably distinct.

Furthermore, searching of the inventions of Groups I through IV together impose a serious search burden. In the instant case, the search of all four compositions are not coextensive. There is a search burden in the non-patent and the patent literature. There may be journal articles or patents devoted to either the carriers, linkages, polynucleotides or the complexes of each Group. Searching for one Group is therefore not coextensive for the other Groups. The search of a particular immunomodulatory polynucleotide of the motif claimed would not likely result in a coextensive search of either the linkages, microcarriers or pharmaceutical compositions claimed. As such, it would be burdensome to properly search the inventions encompassed by all of the Groups claimed.

Claim 1 link(s) inventions recited in claims 2, 3, 4 and 5, of Groups I, II, III and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the

claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the

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Group is **703-872-9306**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JZ

12-13-04

*J Zara TC1600*